

Fundamental / applied research

Discovery of imaging biomarker with clinical potential

Redirect research effort elsewhere

Sensitivity and specificity expected to be sufficient for clinical utility? ("credentialed biomarker")

Does envisioned clinical need justify expenditure of resources?

Is it feasible to develop the agent or imaging technique?

Is there an existing imaging platform for the agent or technique?

Developmental Pathway

Image-Based Risk Assessment Agent / Technique

Biomarkers for Screening, Diagnosis, Staging, Response Assessment, Prognosis, Prediction

NCI TRWG version 041707

Box = Action
Diamond = Decision

Develop necessary new imaging platform (iterative with development of agent / technique)

Does the agent require radiolabeling?

Is the innovation an agent or a technique?

Perform radiolabeling, dosimetry, etc.

Test / refine imaging performance, PK/PD, toxicology, etc. in preclinical setting

Optimize acquisition and analytic parameters in preclinical or Phase 0 setting

Can it be fixed?

Preclinical performance adequate?

Does new or optimized existing system or platform need regulatory approval?

Establish GMP production for agent if necessary

Pre-IDE meeting for platform if necessary

Establish GMP manufacturing if necessary

Submit IND if necessary

Clinical study required for regulatory approval?

Optimized platform available for clinical testing, file 510(k) if necessary

File IDE if necessary, perform study

Test / refine imaging performance, PK/PD, toxicology, etc. in Phase I/II setting

Regulatory approval

Can it be fixed?

Clinical performance adequate?

Phase II+ trials for specific clinical utilities

